

REMARKS

Non-elected dependent claims 4, 58, 59, 61, 65, 66, 68-71, 73, 75, 77, 79, 88, 89, 102, and 104 also have been canceled without prejudice or disclaimer. Non-elected species claims 2, 87, 90-93, 101, 103, and 109-110 are withdrawn by the examiner. In order to expedite the prosecution, applicants cancel the withdrawn claims without prejudice or disclaimer. For clarity and to avoid extensive amendments to the claims, applicants cancel claims 1-124, without prejudice or disclaimer, and submit a new set of claims. Claims 125-186 are new and pending in this application. Independent new claims 125, 155, and 170 are directed to the corresponding subjected matters of the cancelled independent claims 11, 97, and 105, respectively. Therefore, all new claims fall under the elected group. Support for the new claims can be found throughout the specification. No new matter is introduced. The Office Action is discussed below:

Indefiniteness Rejections:

Claims 1, 3, 7-8, 11-14, 22-24, 26, 29-30, 32, 36-39, 60, 62-64, 67, 72, 74, 76, 78, 80-86, 94-100, 105-108, and 111-112 are rejected under 35 U.S.C. 112, second paragraph, allegedly as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is moot as the claims are cancelled without prejudice or disclaimer. However, applicants mention that the new independent claims recite blending of polymeric material with one or more additives. Applicants also mentions that the new claims do not recite the phrase "or the like", or "at least 10-1000 MPa".

Anticipation and Obviousness Rejections:

On pages 3-4 of the Office Action, the examiner rejects claims 99-100 under 35 U.S.C. 102(b) allegedly as being anticipated by Saum *et al.* (US 2002/0107300).

On page 4-5 of the Office Action, the examiner rejects claims 105-106 and 112 under 35 U.S.C. 102(b) allegedly as being anticipated by Mckellop *et al.* (WO 99/52474).

On page 5-9 of the Office Action, the examiner rejects claims 1, 3, 7, 29-30, 32, 36-39, 60, 72, 74, 76, 97, and 111 under 35 U.S.C. 103(a) allegedly as being unpatentable over Saum *et al.* (US 2002/0107300).

On page 9-19 of the Office Action, the examiner rejects claims 8, 11-14, 22-24, 62-64, 67, 78, 80-86, 94, 95-96, 97-98, 99-100, 107-108, and 113-115 under 35 U.S.C. 103(a) allegedly as being unpatentable over Saum *et al.* (US 2002/0107300) in view of Lidgren *et al.* (US 6,448,315).

On page 19-22 of the Office Action, the examiner rejects claims 114 and 116-124 under 35 U.S.C. 103(a) allegedly as being unpatentable over Saum *et al.* (US 2002/0107300) in view of Lidgren *et al.* (US 6,448,315) and in view of Mckellop *et al.* (WO 99/52474).

Applicants respectfully disagree with the examiner. Applicants mention that claims 1-124 have been cancelled without prejudice or disclaimer, therefore the rejections are moot.

However, in order to assist the examiner in distinguishing the claimed invention from the cited references applicants submit the following clarifications that the claimed inventions are not anticipated by nor are obvious in view of Lidgren and/or Saum and/or Mckellop.

Lidgren's doping process is different

Lidgren requires doping of vitamin E in presence of supercritical CO₂ (see col. 3, lines 43-62, for example). However, instant claims do not recite supercritical fluid or CO₂.

In addition, Lidgren does not teach the use of consolidated forms of polyethylene nor does it teach about the effects of irradiation on consolidated forms with vitamin E.

Lidgren also does not teach mechanical annealing nor warm irradiation to prevent oxidation.

Saum teaches away

Saum actually discourages one from using antioxidants or additive generally. Applicants refer the examiner to Saum's disclosure that states: "The UHMWPE preform material does not contain stabilizers, antioxidants, or other chemical additives which may have potential adverse effects in medical applications." (see page 2, at [0012]). Thus, Saum teaches away from using additives generally. See *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994) (stating, "[a] reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant"). Therefore, by reading Saum, one skilled in the art would not consider use of an additive. Thus, there is no motivation to combine Saum in order to rectify the deficiencies of Lidgren, which are identified by the examiner.

Regarding a radiation process, Saum teaches low dose radiation for sterilization and not for cross-linking. Saum states: "By separating the irradiation cross-linking step from the sterilization step, the current invention allows one to use lower levels of irradiation for cross-linking than would be effective for sterilization of UHMWPE." (see page 1, at [0008]).

The examiner admits that Saum does not teach the irradiation step after the heating/pressurization process, that is, Saum does not teach the claimed process steps in the same order of instant claims, see claim 8, for example.

Further, applicants submit that the pressure according to Saum would not lead to deformation. Thus, saum does not anticipate the claimed invention nor a combination of Saum with Lidgren would not make the claimed invention obvious.

McKellop

McKellop does not anticipate nor rectify the deficiencies of Lidgren or Saum.

McKellop's process involves blending with peroxide, which does not make oxidation-resistant polyethylene. Therefore, McKellop does not anticipate nor a combination of McKellop with the cited references would not make the claimed invention obvious.

Applicants submit that the cited references do not teach or suggest all claim limitations of the independent claims and refer to the MPEP that:

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

See, MPEP § 2143.03 at 2100-142 (Rev. 6, September 2007).

Not only must all of the elements recited in the claim be present, the elements must be "arranged or combined in the same way" as recited in the claim in order for anticipation to be found. *Net MoneyIN Inc. v. VeriSign Inc.*, Appeal No. 07-1565 (Fed. Cir., October 20, 2008).

Applicants point out, the examiner has admitted that "the instant application and cited references do not do the claimed steps in order", accordingly a *prima facie* case of obviousness is not established.

In view of the above clarifications, applicants request the examiner to consider the MPEP § 2143.01 (II-V) (8th ed. July 2008) that:

The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art, and all teachings in the prior art must be considered to the extent that they are in analogous arts. Where the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another. *In re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991) ...

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007)...

A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art" at the time

the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)...

A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). [R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)...

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)"

Applicants have explained above, even if the cited references were combined, would not yield the claimed method nor the claimed medical implant. Besides, as clarified above, Saum teaches away from using a key ingredient, additive (antioxidant), and thus actually discredits Lidgren. McKellop does not rectify the deficiencies of Saum or Lidgren, as discussed above. Therefore, the cited references do not anticipate nor make the claimed invention obvious.

In view of the above, applicants request withdrawal of the anticipation and obviousness rejections.

Double Patenting Rejection:

On page 22-23 of the Office Action, the examiner provisionally rejects claims 3, 8, 63, and 95-98 on the ground of non-statutory obviousness-type double patenting allegedly as being unpatentable over claims 3, 8, 10, 14, and 16 of co-pending application No. 11/15/06 [sic]. Applicants submit that since a notice of allowability has not been issued for the co-pending application, the merits of this provisional rejection need not be discussed with the examiner at this time. See MPEP § 822.01.

Applicants mention that the rejection is moot as claims 1-124 are cancelled, without prejudice or disclaimer. Applicants also submit that upon acceptance of the claims by the examiner, the provisional obviousness-type double patenting rejection should be withdrawn.

REQUEST

Applicants submit that claims 125-186 are in condition for allowance and request consideration to that effect. The examiner is invited to contact the undersigned at 202-628-6600 should there be any questions.

Respectfully submitted,



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